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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/637,962	08/11/00	THOMPSON	L 500731.01

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EXAMINER	
DEBERRY,R	
ART UNIT	**PAPER NUMBER**
1647	7

DATE MAILED: 10/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/637,962	Applicant(s) THOMPSON, LAWRENCE H.	
	Examiner Regina M. DeBerry	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-116* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-116* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to a method of treating fatigue comprising administering a therapeutic amount of a recombinant erythropoietin, classified in class 514, subclass 2.

II. Claims 16-29, drawn to a method of treating body or other pain comprising administering a therapeutic amount of a recombinant erythropoietin, classified in class 514, subclass 2.

III. Claims 30-38, drawn to a method of treating a symptom in a subject comprising administering at a frequency of once per week or less a therapeutic amount of a recombinant erythropoietin, classified in class 514, subclass 2.

IV. Claims 39-65, drawn to a method of treating a symptom in a subject having a condition adversely effected by a side effect of treatment with erythropoietin comprising, administering a therapeutic amount of a recombinant erythropoietin, classified in class 514, subclass 2.

V. Claims 66-89, drawn to a method of treating or preventing an anemic condition in a subject comprising, administering a therapeutic amount of a recombinant erythropoietin wherein subject is non-responsive or adversely effective by treatment with Epoetin Alfa or Beta, classified in class 514, subclass 2.

VI. Claims 90-92, drawn to a formulation or kit comprising a therapeutic amount of Epoetin Omega, classified in class 530, subclass 395.

VII. Claims 93-115, drawn to a method of treating or preventing an anemic condition in a subject, comprising administering a therapeutic amount of recombinant erythropoietin without producing or exacerbating an adverse effect selected from the group consisting of increased blood pressure or hypertension, classified in class 514, subclass 2.

VIII. Claim 116, drawn to a method of treating a patient comprising administering to the patient having a need thereof a recombinant erythropoietin, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-V,VII,VIII are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. In addition the methods are drawn to treatment in different populations of subjects. Therefore, a search and examination of all seven methods in one patent application would result in an undue burden, since the searches for the seven methods are not co-extensive, the classification is different, and the subject matter is divergent.

Inventions VI (product) and I-V, VII, VIII (process of using) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially different process such as in making antibodies.

Claims 2, 17, 30, 39, 66 and 93 are generic to a plurality of disclosed patentably distinct species comprising recombinant erythropoietin. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If Group I is elected: Applicant is required to elect a condition associated with fatigue. Claims 4-8, 10,11 are generic to a plurality of disclosed patentably distinct species comprising cancer, liver dysfunction, hepatitis infection, heart condition, autoimmune disease, chronic fatigue and cancer therapy. Applicant is required under

35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If Group II is elected: Applicant is required to elect a condition associated with vascular pain. Claims 19-23, 25 are generic to a plurality of disclosed patentably distinct species comprising cancer, liver, hepatitis infection, heart condition, autoimmune disease and cancer therapy. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If Group III is elected: Applicant is required to elect a condition associated with a symptom. Claims 34-38 are generic to a plurality of disclosed patentably distinct species comprising anemia, fatigue, dementia, and vascular pain. Applicant is required

under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If Group IV is elected:

Applicant is required to elect a symptom. Claims 41-45,61 are generic to a plurality of disclosed patentably distinct species comprising anemia, fatigue, dementia, vascular pain and cancer therapy. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Applicant is required to elect an adverse side effect. Claims 46-48 are generic to a plurality of disclosed patentably distinct species comprising increased blood pressure or hypertension, thrombosis and increased platelet count.

Applicant is required to elect a condition. Claims 49-51,53-55 are generic to a plurality of disclosed patentably distinct species comprising hypertension, thrombosis, heart condition, cancer, autoimmune disease, liver dysfunction, hepatitis and treatment by chemotherapy or radiation therapy.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If Group V is elected: Applicant is required to elect an anemic condition. Claims 68,72-75 and 86 are generic to a plurality of disclosed patentably distinct species comprising anemia associated with renal anemia, malignant disease, chemotherapy, chronic disease, AIDS, prematurity, thalasemia, autoimmune hemolytic disease, aplastic anemia, heart condition, liver dysfunction, hepatitis, cancer and cancer therapy. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If Group VII is elected: Applicant is required to elect an anemic condition. Claims 95,102-105 are generic to a plurality of disclosed patentably distinct species comprising anemia associated with renal anemia, malignant disease, chemotherapy, chronic disease, AIDS, prematurity, thalasemia, autoimmune hemolytic disease, aplastic anemia, heart condition, liver dysfunction, hepatitis and cancer. Applicant is

required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If Group VIII is elected: Applicant is required to elect a liver impairment. Claim 116L is generic to a plurality of disclosed patentably distinct species comprising hepatitis, cirrhosis, autoimmune disease, chemical liver dysfunction and pathological liver dysfunction. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and/or recognized divergent subject matter, restriction for

examination purposes as indicated is proper. To be fully responsive to this requirement, Applicants are **required** to point out which claims correspond to the elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD
RMD
October 2, 2001

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER